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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,763	11/17/2000	Victor E. Shashoua	CMX-001. US	7035

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EXAMINER

DESAI, ANAND U

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 07/25/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/715,763

Applicant(s)

SHASHOUA, VICTOR E.

Examiner

Anand U Desai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) _____ is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-103 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Form PTO-1472*.

DETAILED ACTION

Election/Restrictions

The inventions are distinct, each from the other because of the following reasons:

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 1. Claims 1, 15-18, 19-24, and 70-87, drawn to
R₁ Gln Tyr Lys Leu Gly Ser Lys Thr Gly Pro Gly Gln R₂ (SEQ ID NO: 1),
classified in class 530, subclass 300.
 2. Claims 2, 15-18, 19-24, and 70-87, drawn to
R₁ Gln Thr Leu Gln Phe Arg R₂ (SEQ ID NO: 2), classified in class 530,
subclass 300.
 3. Claims 3, 4, 15-18, 19-24, and 70-87, drawn to peptide compounds comprising,
Asp Gly,
Asp Gly Asp,
Asp Gly Asp Gly Asp (SEQ ID NO: 4),
Asp Gly Asp Gly Phe Ala (SEQ ID NO: 5),
Asp Gly Asp Gly Asp Phe Ala (SEQ ID NO: 6),
Asp Gly Asp Gly Asp Phe Ala Ile Asp Ala Pro Glu (SEQ ID NO: 16), classified
in class 530, subclass 300.
 4. Claims 3, 4, 15-18, 19-24, and 70-87, drawn to peptide compounds comprising,
Asp Gly,
Asp Gly Asn,
Asp Gly Asn Gly Asp Phe Ala (SEQ ID NO: 7),

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- Asn Gly Asn Gly Asp (SEQ ID NO: 18), and
- Asn Gly Asn Gly Phe Ala (SEQ ID NO: 22), classified in class 530, subclass 300.
5. Claims 3, 4, 15-18, 19-24, and 70-87, drawn to peptide compounds comprising,
- Asn Gly,
- Asn Gly Asn,
- Asn Gly Asn Gly Asp Phe Ala (SEQ ID NO: 8),
- Asn Gly Asn Gly Asp (SEQ ID NO: 17), and
- Asn Gly Asn Gly Phe Ala (SEQ ID NO: 21), classified in class 530, subclass 300.
6. Claims 3, 4, 15-18, 19-24, and 70-87, drawn to peptide compounds comprising,
- Asn Gly,
- Asn Gly Asp,
- Asn Gly Asp Gly Asp Phe Ala (SEQ ID NO: 9),
- Asn Gly Asp Gly Asp (SEQ ID NO: 19),
- Asn Gly Asp Gly (SEQ ID NO: 20), and
- Asn Gly Asp Gly Phe Ala (SEQ ID NO: 23), classified in class 530, subclass 300.
7. Claims 5, 15-18, 19-24, and 70-87, drawn to peptide compounds comprising
- Asn Ser Thr, classified in class 530, subclass 300.
8. Claims 6, 15-18, 19-24, and 70-87, drawn to peptide compounds comprising
- Phe Asp Gln, classified in class 530, subclass 300.
9. Claims 7, 8, 15-18, 19-24, and 70-87, drawn to peptide compounds comprising
- Ser Lys Met Thr Leu Thr Gln Pro (SEQ ID NO: 12),
- classified in class 530, subclass 300.

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10. Claims 9-11, 15-18, 19-24, and 70-87, drawn to peptide compounds defined by the formula of claim 9,

$R_1 \text{ Xaa}_1 \text{ Xaa}_2 \text{ Xaa}_3 \text{ R}_2$, wherein Xaa_1 is Asp, Asn, Glu, Gln, Thr, or Tyr; Xaa_2 is absent or any amino acid; Xaa_3 is Asp, Asn, Glu, Thr, Ser, Gly, or Leu, classified in class 530, subclass 300.

At least 882 peptides are set forth in the formula presented in claim 9. These peptides differ in structure because the sequences provided in these claims comprise non-conservative amino acid substitutions. Thus, overlapping sequences have been selected for inventions 1-26 and the peptide sequences in each of inventions 1-26 are considered to be patentably distinct. If anyone of inventions 1-26 is elected, the elected invention will only be examined in-so-far as it pertains to the sequences listed therein. This is not a species election.

If Applicants elect Invention 10, Applicants must also provide the sequence that they wish to be examine. Because the peptides are considered patentably distinct, this is NOT a species election.

11. Claims 12, 15-18, 19-24, and 70-87, drawn to peptide compounds defined by the formula of claim 12,

$R_1 \text{ Leu Xaa}_1 \text{ Xaa}_2 \text{ R}_2$, wherein Xaa_1 is any amino acid; Xaa_2 is Gln, Gly, or Tyr, classified in class 530, subclass 300.

At least 63 peptides are set forth in the formula presented in claim 12. These peptides differ in structure because the sequences provided in these claims comprise non-conservative amino acid substitutions. Thus, overlapping sequences have been selected

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for inventions 1-26 and the peptide sequences in each of inventions 1-26 are considered to be patentably distinct. If anyone of inventions 1-26 is elected, the elected invention will only be examined in-so-far as it pertains to the sequences listed therein. This is not a species election.

If Applicants elect Invention 11, Applicants must also provide the sequence that they wish to be examine. Because the peptides are considered patentably distinct, this is NOT a species election.

12. Claims 13, 14, 15-18,19-24, and 70-87, drawn to peptide compounds comprising Met Thr Leu, classified in class 530, subclass 300.

13. Claims 13, 14, 15-18,19-24, and 70-87, drawn to peptide compounds comprising Met Thr Asp or Met Thr Glu, classified in class 530, subclass 300.

14. Claims 13, 14, 15-18,19-24, and 70-87, drawn to peptide compounds comprising Met Thr Asn or Met Thr Glu, classified in class 530, subclass 300.

15. Claims 13, 14, 15-18,19-24, and 70-87, drawn to peptide compounds comprising Met Thr Thr, classified in class 530, subclass 300.

16. Claims 19-24, and 70-87, drawn to peptide compounds comprising Glu Thr Leu Gln Phe Arg (SEQ ID NO: 13), classified in class 530, subclass 300.

17. Claims 19-24, and 70-87, drawn to peptide compounds comprising Gln Tyr Ser Ile Gly Gly Pro Gln (SEQ ID NO: 14), classified in class 530, subclass 300.

18. Claims 19-24, and 70-87, drawn to peptide compounds comprising

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Ser Asp Arg Ser Ala Arg Ser Tyr (SEQ ID NO: 15), classified in class 530, subclass 300.

19. Claims 19-24, and 70-87, drawn to peptide compounds comprising Thr Val Ser, classified in class 530, subclass 300.

20. Claims 19-24, and 70-87, drawn to peptide compounds comprising Leu Thr Gln, classified in class 530, subclass 300.

21. Claims 19-24, and 70-87, drawn to peptide compounds comprising Leu Thr Gly, classified in class 530, subclass 300.

22. Claims 19-24, and 70-87, drawn to peptide compounds comprising Leu Thr Tyr, classified in class 530, subclass 300.

23. Claims 19-24, and 70-87, drawn to peptide compounds comprising Glu Gly,
Glu Ala, classified in class 530, subclass 300.

24. Claims 19-24, and 70-87, drawn to peptide compounds comprising Gln Gly,
Gln Ala, classified in class 530, subclass 300.

25. Claims 19-24, and 70-87, drawn to peptide compounds comprising Asp Ala, classified in class 530, subclass 300.

26. Claims 19-24, and 70-87, drawn to peptide compounds comprising Asn Ala, classified in class 530, subclass 300.

The claims comprise peptides that differ in structure because the sequences provided in these claims comprise non-conservative amino acid substitutions. Thus, overlapping sequences have been selected for inventions 1-26. The peptide sequences in each of inventions 1-26 are

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considered to be patentably distinct. If anyone of inventions 1-26 is elected, the elected invention will only be examined in-so-far as it pertains to the sequences listed therein. This is not a species election.

If anyone of Inventions 1-26 is elected, and sequences of the other 25 happens to be found in the search of the elected invention, the Examiner will rejoin the invention comprising the found sequence with the elected Invention.

27-52. Claims 25-28, drawn to a method of upregulating expression of a gene encoding an superoxide dismutase by administering the peptide compounds of any one of Inventions 1-26, respectively.

53-78. Claims 29-34, drawn to a method of counteracting the oxidative effects of reactive oxygen species and free radicals in mammalian cells or tissues by administering the peptide compounds of any one of Inventions 1-26, respectively.

79-104. Claims 35-39, drawn to a method of reducing or preventing an undesirable elevation in the levels of reactive oxygen species and other free radicals in cells or tissues by administering the peptide compounds of any one of Inventions 1-26, respectively.

105-130. Claims 40-51, and 62-69, drawn to a method of treating a disease or condition exhibiting an undesirable elevation in levels of reactive oxygen species or other free radicals by administering the peptide compounds of any one of Inventions 1-26, respectively.

131-156. Claims 52-56, drawn to a method of treating pain in an individual by administering the peptide compounds of any one of Inventions 1-26, respectively.

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157-182. Claims 57-61, drawn to a method of stimulating or upregulating levels of AP1 transcription factor by administering the peptide compounds of any one of Inventions 1-26, respectively.

183-208. Claims 88-103, drawn to a method of making a dietary supplement composition comprising making peptides of Inventions 1-26, respectively.

2. The inventions are distinct, each from the other because:

3. Inventions of peptide compounds (1-26) and method of uses (27-52, 53-78, 79-104, 105-130, 131-156, or 157-182) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptide products could be used in a materially different process such as demonstrated in Inventions of method of upregulating expression of a gene encoding an superoxide dismutase (27-52), method of counteracting the oxidative effects of reactive oxygen species and free radicals in mammalian cells or tissues (53-78), method of reducing or preventing an undesirable elevation in the levels of reactive oxygen species and other free radicals in cells or tissues (79-104), method of treating a disease or condition exhibiting an undesirable elevation in levels of reactive oxygen species or other free radicals (105-130), method of treating pain in an individual (131-156), method of stimulating or upregulating levels of AP1 transcription factor (157-182).

4. Inventions of method of making dietary supplement (183-208) and peptide compounds (1-26) are related as process of making and product made. The inventions are distinct if either or

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both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the peptide compound can be made by peptide synthesis, or recombinant techniques, for example.

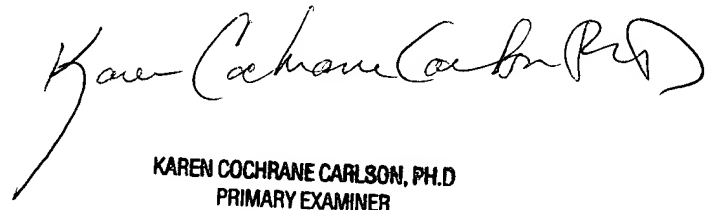
5. The methods of Inventions 27-208 require different products and/or comprise wholly different steps to achieve their respective end results. Therefore, Inventions 27-208 are patentably distinct one from the other.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai whose telephone number is (703) 305-4443. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

July 23, 2003


KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER